

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

IN RE: TAXOTERE (DOCETAXEL))	MDL No. 16-2740
PRODUCTS LIABILITY)	
LITIGATION)	SECTION: "H" (5)
)	
This document relates to:)	
Elizabeth Kahn, 16-17039)	

ORDER AND REASONS

Before the Court is Plaintiff's Motion to Reconsider Order Regarding Dr. Madigan's Meta-Analysis of Observational Studies (Doc. 12195). For the following reasons, the Motion is **DENIED**.

BACKGROUND

Plaintiffs in this multidistrict litigation ("MDL") are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,¹ that Plaintiffs were administered for the treatment of breast cancer or other forms of cancer. Among these companies are Defendants sanofi-aventis U.S. LLC and Sanofi U.S. Services Inc. (collectively, "Sanofi" or "Defendants"). Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss. Plaintiffs bring claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more. The first bellwether trial was held in September 2019, and the second trial is set for 2021.²

On January 29, 2021, the Court issued its Order and Reasons on Defendants' Motion to Exclude Expert Testimony on Dr. David Madigan (Doc. 12098). In pertinent part, the Court ruled that Dr. David Madigan, Plaintiff

¹ Docetaxel is the generic version of Taxotere.

² The second trial was continued due to the COVID-19 pandemic.

Elizabeth Kahn's expert biostatistician for the June trial, will not be permitted to testify about his meta-analysis of four observational studies. In the instant Motion, Plaintiff Kahn moves the Court to reconsider this ruling and permit Dr. Madigan to rely on his meta-analysis. Sanofi opposes the Motion.

LEGAL STANDARD

In her Motion, Plaintiff does not identify the standard that the Court should apply here, and in its opposition, Sanofi asks the Court to apply Federal Rule of Civil Procedure 59(e). The Court, however, finds that the applicable standard is Rule 54(b), relating to interlocutory orders.³ "Under Rule 54(b), 'the trial court is free to reconsider and reverse its decision for any reason it deems sufficient, even in the absence of new evidence or an intervening change in or clarification of the substantive law.'"⁴ Rule 54(b), however, does not give the Court unlimited power to consider new arguments.⁵ "Any position is supportable by boundless arguments," but "[j]udicial economy counsels against reconsidering an issue each time someone presents a new argument."⁶ "When there exists no independent reason for reconsideration other than mere disagreement with a prior order, reconsideration is a waste of judicial time and resources and should not be granted."⁷

³ FED. R. CIV. P. 54(b) (noting that a district court may revise at any time prior to final judgment "any order . . . that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties"). See *McClendon v. United States*, 892 F.3d 775, 781 (5th Cir. 2018).

⁴ *Austin v. Kroger Texas, L.P.*, 864 F.3d 326, 336 (5th Cir. 2017) (quoting *Lavespere v. Niagara Mach. & Tool Works, Inc.*, 910 F.2d 167, 185 (5th Cir. 1990)).

⁵ *Livingston Downs Racing Ass'n, Inc. v. Jefferson Downs Corp.*, 259 F.Supp.2d 471, 480 (M.D. La. 2002).

⁶ *Id.* at 481.

⁷ *Hightower v. Group 1 Automotive, Inc.*, 2016 WL 3430569, at *3 (E.D. La. June 22, 2016).

LAW AND ANALYSIS

In its Order and Reasons, the Court ruled that Dr. Madigan could not testify about his meta-analysis of four observational studies. The Court found it significant that Dr. Madigan has published work describing the “biases and sources of variability” that can “undermine the validity of epidemiologic analysis of observational databases.”⁸ He has written that “observing large heterogeneity should raise questions about the ability of observational data to address the clinical question at all.”⁹

Plaintiff now argues that the Court wrongly assumed that Dr. Madigan conceded the existence of large heterogeneity in his meta-analysis. She avers that Dr. Madigan never made such a concession. She explains now that Dr. Madigan “fully investigated and accounted for statistical heterogeneity,” and she asserts that “the heterogeneity here is not statistically significant.”¹⁰ She further avers that even though the heterogeneity is not large, “Dr. Madigan thoroughly examined any ‘questions’ that the heterogeneity might raise.”¹¹

The Court is puzzled by Plaintiff’s Motion. The Court did not make any assumption about heterogeneity in ruling on Defendants’ Motion to Exclude Expert Testimony on Dr. David Madigan (the “Motion to Exclude”). Instead, the Court was guided by Plaintiff’s opposition to the Motion to Exclude. In it, Plaintiff herself described “a relatively high heterogeneity” in Dr. Madigan’s evidence, and Plaintiff averred that “the limitations of a meta-analysis of observational studies are proper for cross examination.”¹² Even now, in the instant Motion, Plaintiff quotes testimony from Dr. Madigan admitting that

⁸ Doc. 12098 at 12.

⁹ *Id.*

¹⁰ Doc. 12195-1 at 3, 4.

¹¹ *Id.* at 4.

¹² Doc. 11086 at 7.

“there is some between-study heterogeneity” here.¹³ He states that it “is not quite statistically significant, but it’s close.”¹⁴

Again, the Court is guided by Dr. Madigan’s own words:

Many different potential biases and sources of variability can undermine the validity of epidemiologic analysis of observational databases. Even when holding data source constant, heterogeneity can persist, presumably because of observed and unobserved patient characteristics that vary across databases.

[. . .]

[I]dentifying specific elements that explain variability across observational data can prove challenging. Certainly, deriving a composite estimate in the face of significant heterogeneity should be discouraged. Moreover, observing large heterogeneity should raise questions about the ability of observational data to address the clinical question at all.¹⁵

The Court refuses to reconsider this issue based on Plaintiff’s new argument attempting to recharacterize the level of heterogeneity here. In its Order and Reasons, the Court ruled that if Dr. Madigan were to rely on his meta-analysis, he would not be employing the same level of intellectual rigor that characterizes his practice in the relevant field. The Court still finds this to be true. It is apparent that Plaintiff merely disagrees with this, and such disagreement does not warrant this Court’s reconsideration.

¹³ Doc. 12195-1 at 3 n.11.

¹⁴ *Id.*

¹⁵ Doc. 12098 (quoting Doc. 11003-18 at 4–6).

CONCLUSION

For the foregoing reasons, Plaintiff's Motion to Reconsider Order Regarding Dr. Madigan's Meta-Analysis of Observational Studies (Doc. 12195) is **DENIED**.

New Orleans, Louisiana, this 7th day of April, 2021.



JAME TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE